DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Washington DC 20204

APR 26 2001

WARNING LETTER
ONPLDS 10-01

Damon DeSantes
CEO
Richardson Labs, Inc.
851 Broken Sound Parkway, NW
Boca Raton, Florida 33487

Dear Mr. DeSantes:

The Food and Drug Administration (FDA) has reviewed the label for Carbo Solutions™ High Protein Bar. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR).

The product is adulterated under section 402(a)(2)(C) of the Act because it contains cholecalciferol (Vitamin D3) which is an unapproved food additive when used in this product. Cholecalciferol (Vitamin D3) has been affirmed to be generally recognized as safe when used in accordance with 21 CFR 184.1950. Because of safety concerns raised by a cumulative dose that could result from multiple additions to foods, the regulation restricts use to the limitations specified, in accordance with 21 CFR 184.1(b)(2).

This product is misbranded because the label bears nutrient content claims that are not authorized by regulation or the Act. The claims include "For Low Carb Diets Only 2 Carbs!" (Section 403(r)(1)(A)).

The product is further misbranded because the label bears the statement "Glycerine, polydextrose, xylitol, maltitol....have been omitted from the "Total Carbohydrate" count....". Glycerine, polydextrose, xylitol and maltitol are carbohydrates and must be included in the value declared for "Total Carbohydrates" in nutrition labeling (Sections 403(a), 403(q) and 21 CFR 101.9(c)(6)).

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be

completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition